DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
297 Plus Park Blvd
Nashville, TN 37217

Telephone: 615-781-5380
FAX: 615-781-5391

July 13, 2006

WARNING LETTER NO. 2006-NOL-13

FEDERAL EXPRESS
OVERNIGHT DELIVERY

James K. Lee, CEO
Advanced Medical Systems, Inc.
2714 19th Place South
Birmingham, Alabama 35209

Dear Mr. Lee:

On February 14, 2006, a United States Food and Drug Administration (FDA) investigator inspected your firm located at 2714 9th Place South, Birmingham, Alabama. Our investigator determined your firm manufactures catheters. Cholangio catheters are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 United States Code (USC) 321(h)].

The inspection revealed your devices are adulterated under section 501(f)(1)(B) of the Act [21 USC 351(f)(1)(B)], as they are class III devices under section 513(f) of the Act [21 USC 360c(f)], and do not have an approved application for premarket approval in effect pursuant to section 515(a) of the Act [21 USC 360e(a)] or an approved application for an investigational device exemption under section 520(g) of the Act [21 USC 360j(g)]. For a product requiring premarket approval before marketing, the notification required by section 510(k) of the Act [21 USC 360(k)], is deemed to be satisfied when a premarket approval application is pending before the FDA.

Your devices are also misbranded under section 502(o) of the Act [21 USC 352(o)] as they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the Act [21 USC 360], were not included in a list required by section 510(j) of the Act [21 USC 360(j)], and a notice or other information respecting the devices was not provided to the FDA as required by section 510(k) of the Act [21 USC 360(k)].

It is our understanding all Cholangio catheters have been removed from the market. You also told our investigator you ceased having these catheters manufactured by your contract manufacturer. Should you resume manufacturing and marketing these catheters without first obtaining FDA premarket clearance or approval and without registering and listing under section 510 of the Act [21 USC 360], the catheters will be adulterated and misbranded as explained above.

This letter may not list all the deficiencies at your facility. You are responsible for ensuring your firm adheres to all requirements of the Act and regulations. Federal agencies are advised of the issuance of all warning letters about devices so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action including seizure, injunction, and/or civil money penalties without further notice.

Please respond in writing within fifteen (15) working days of your receipt of this letter outlining the specific steps you have taken to bring your firm into compliance with the law. Your response should include each step taken to correct the violations and prevent their recurrence. If you cannot complete all corrections within 15 working days, we expect you to explain the reason for the delay and state when any remaining deviations will be corrected.

Please send your reply to the U.S. Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, 2424 Edenborn Avenue, Suite 410, Metairie, Louisiana 70001. If you have questions regarding issues in this letter, please contact Ms. Asente at (504) 219-8818, extension 104.

Sincerely,

Carol S. Sanchez
Acting District Director
New Orleans District